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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,089	04/12/2004	Signe Erickson Varner	56086CON2 (71699)	3168
21874	7590	07/24/2006	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			HUH, BENJAMIN	
			ART UNIT	PAPER NUMBER

3767

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/823,089	Applicant(s) VARNER ET AL.	
	Examiner Benjamin Huh	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 4/17/06.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 82-91 and 103 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 82-91 & 103 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 82-89, 91, & 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenman et al (US Patent No. 6478776 B1) in view of Rosenwald (US Patent No. 4678466). The Rosenman et al reference discloses a method for treating a patient comprising providing a delivery device comprising a non-linear shaped, body member 12 having at least two deviations from a linear path and a therapeutic substance; and inserting into a patient the device whereby the body member resides in the patient and a therapeutic substance is administered to the patient via the body member, see abstract, col. 3 line 67 – col. 4 line 32, col. 5 lines 40 – col. 12 line 23, figures 4-5 & 8-19. Now even though Rosenman does not explicitly disclose that the device is inserted into the ear and resides in the patient ear attention is directed to Rosenwald. The Rosenwald reference teaches the use of a drug delivery device that can be inserted in multiple areas such as the eye or the ear in order to provide medication to the desired location, see col. 9 lines 12-21. therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to utilize the device

of Rosenman to treat a patient by administering a therapeutic substance to the patient via the device in any desired location for proper treatment.

With respect to claims 83-85, wherein the device body member can be seen to have at least five deviations from a linear path in figures 4-5.

With respect to claims 86-87, wherein the device body comprises a helical shape and has a substantially Z-shape in figures 4-5 & 8-19.

With respect to claims 88-89, wherein the body member comprises a polymer and comprises a therapeutic substance that can be delivered to the patient, see col. 10 lines 21-36 & col. 15 line 9 – col. 16 line 35.

With respect to claim 91, wherein the device length is about 1.5 cm or less, see col. 9 lines 31-37.

Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenman et al (US Patent No. 6478776 B1) in view of Rosenwald (US Patent No. 4678466) and further in view of Johnson (US Patent No. 5972027). Now even though Rosenman in view of Rosenwald does not explicitly disclose the device comprising a shape memory material attention is directed to Johnson. The Johnson reference teaches an implantable drug delivery device with a non-linear shaped body member that can be made of nitinol, a very well known shape memory alloy of nickel-titanium, see col. 2 lines 39-56. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device and use of Rosenman in view of Rosenwald to

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utilize the teachings of Johnson to comprise the device of a shape memory material in order to provide a bio-compatible and strong device.

### ***Response to Arguments***

Applicant's arguments with respect to claims 82-91 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

